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PROMEX technologies LLC

SECTION 5

510(k) SUMMARY:

Date: 21-June-2011

510(k) Owner:

Promex Technologies, LLC
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Contact:

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Names:

Trade Name – Full Core Biopsy System
Common Name – Kit, Needle Biopsy
Classification Name – Gastroenterology-Urology Biopsy Instrument
21 CFR 876.1075, Product Code FCG

Legally Marketed Devices of Equivalence:

K011270 – SABD™ Automated Core Biopsy Device (Promex Technologies, LLC) (the "SABD™ Predicate")
K904987 - Vibronics Auto Core Biopsy Device (also known as BioPince® Full Core Biopsy Instrument - currently sold by Medical Device Technologies, Inc.) (the "BioPince® Predicate)

Device Description:

The Full Core Biopsy System (the "System") includes an automatic spring powered Biopsy Device (the "Device") and a Coaxial Introducer (K954265, Promex Technologies, LLC) ("the

Introducer"). As described more fully in the scientific concepts section below, the Device obtains and delivers a core tissue sample. The end-cut design of the Device allows the entire inner diameter of the cutting cannula to be open to capture tissue.

The System (2 components) is comprised of;

1. The Device
2. The Introducer

and are provided sterile in a pouch and intended for single patient use only.

The System will be provided in 16, 18, and 20 gage and the working lengths range from 10cm to 25cm. The Device includes a Franseen-style cutting geometry on the end of the cannula and the Introducer includes a standard trocar tip.

Indications for Use:

The System is intended to be used for soft tissue and tumor biopsy of such organs as the liver, spleen, kidney, prostate, lung, breast, and lymph nodes. When used for breast biopsy, the product is for diagnosis only. The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal of using standard surgical procedures.

Scientific Concepts that Form the Basis for the Device:

The Device has an outer Cutting Cannula having a sharpened tip and an inner stylet. The Cutting Cannula and the inner stylet are both operated manually by the user by a Plunger. In operation, the Introducer is positioned within tissue in a standard fashion. As with the SABD™ Predicate device, the Device is first placed in a Ready condition (prior to introduction to the patient) by pulling back on a Plunger, and then the Device is advanced within the Introducer. The Plunger is first advanced to the first stop. To fire (advance the outer cutting cannula to obtain a biopsy tissue sample), the Plunger is fully depressed. When the Device is fired, the outer Cutting Cannula extends forward and cuts tissue. A tissue specimen is retained within the Cutting Cannula. As with both Predicate devices, the Device is then removed from the Introducer to retrieve the tissue specimen from the Device. From the user perspective, the tissue specimen is delivered from the Device the same as the SABD™ Predicate, by pulling back on the Plunger and then advancing the Plunger forward to the first stop. In a device such as the SABD™ Predicate, this action results in exposure of the sampling notch so that the specimen can be manually removed. With the Device, this action results in the delivery of the tissue specimen from the distal end of the outer Cutting Cannula of the Device, as occurs with the BioPince® Predicate. If it is desired to obtain another tissue specimen, the Device is again placed in the Ready condition by pulling back on the Plunger. From the user perspective, this is identical to how the SABD™ Predicate is used.

Predicate Device Comparison:

The SABD™ Predicate

The Full Core Biopsy System has the same intended use as the SABD™ Predicate. All materials, manufacturing methods, chemical composition of components, and energy source are the same as the predicate SABD™ Predicate. The design is the same as the SABD™ Predicate, with the exception of the cutting feature.

The System uses an end-cut technology on the Device rather than the side-cut technology found in the SABD™ Predicate. The difference in the cutting feature poses no concerns regarding safety and effectiveness, as it is equivalent to the cutting feature of the Biopince® Predicate.

The SABD™ Predicate has a fifty-nine month shelf life. The subject device will have a thirty-six month shelf life. The shorter shelf-life for the subject device is due to marketing purposes. The difference in shelf-life poses no concerns regarding safety and effectiveness.

The Biopince® Predicate

The Full Core Biopsy System has equivalent intended use as the Biopince® Predicate". The end-cut technology (mechanism of cutting tissue) of the Device and delivery of tissue sample (as described above) is equivalent to that of the Biopince® Predicate. The Device has a fixed stroke, which is a simpler construction from the Biopince® Predicate, which has a variable stroke.

Performance Testing:

Bench Testing:

The Full Core Biopsy System was tested in a side-by-side comparison against the SABD™ Predicate and the Biopince® Predicate.

Penetration testing confirms that the penetration force of the System falls between the penetration forces of the SABD™ Predicate and the Biopince® Predicate.

Testing of stroke lengths confirms that the stroke length of the Device is the same as the stroke length of the SABD™ Predicate and has a stroke length that is equivalent to one of the settings of the BioPince® Predicate.

The Full Core Biopsy System was tested in a side-by-side comparison against the SABD™ Predicate which was used in conjunction with a Coaxial Introducer. Testing against the Biopince® Predicate with Coaxial Introducer was also conducted. Test results confirmed that the Full Core Biopsy System would retrieve a tissue sample that was substantially equivalent to the tissue sample retrieved by the predicate devices.

Mechanical Durability Testing:

The Device utilizes the same components, springs, manufacturing processes, and tests as used in the assembly of the SABD™ Predicate. Mechanical Durability testing of the Device will be a part

of the normal inspection process, which is the same as the inspection process for the 510k Owner's SABD™ Predicate.

Sterilization:
The sterilization process will be identical for the System as the SABD™ Predicate. The SABD™ Predicate and the Introducer have been validated for gamma sterilization at a minimum level of 25kGy and a maximum of 50kGy. The process is validated and monitored to a 10^6 SAL per ISO11137-2:2006, method VDmax[25].

Aging Tests:
The SABD™ Predicate has been evaluated for shelf-life stability using accelerated aging as well as real-time shelf exposure under normal storage conditions. All materials, manufacturing methods, and packaging are the same for the subject Device and the SABD™ Predicate; therefore no further testing of the System is necessary.

Conclusion:
The Full Core Biopsy System is safe and effective and performs substantially equivalent to the Predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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% Anson Group
Ms. Allison Scott
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SEP - 6 2011

Re: K111765
Trade/Device Name: Full Core Biopsy System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW, FCG
Dated: June 22, 2011
Received: June 23, 2011

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K111765**

Device Name: Full Core Biopsy System

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Prescription Use ___Yes (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use No (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111765